

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

54-03

12/16/03

Review of Establishment Data by Inspection Program Personnel

I. PURPOSE

The purpose of this notice is to clarify that inspection program personnel have access to a wide range of records under the HACCP regulations (9 CFR part 417), and that they are to request to review certain types of records on a regular basis.

NOTE: This notice does not address Sanitation Standard Operating Procedures (Sanitation SOPs) records verification. All instructions related to verification of Sanitation SOP records are addressed in FSIS Directive 5000.1, Revision 1, Chapter I.

II. BACKGROUND

Under the HACCP regulations, an establishment is required to keep records related to the HACCP plan, including all decisionmaking documentation associated with its development and all records associated with its operation (i.e., monitoring, verification, and corrective action). To develop a HACCP plan, under 9 CFR 417.2(a) (1), an establishment is to have a written hazard analysis that determines the food safety hazards reasonably likely to occur in the production process, identifies the preventive measures the establishment can apply to control those hazards, and includes a flow chart that lists the steps of each process and product flow in the establishment, and that identifies the intended use or consumers of the finished product (9 CFR 417.2(a)(2)). In addition, under 9 CFR 417.5(a)(1), establishments are to maintain "...the written hazard analysis prescribed in 9 CFR 417.2(a) ..., including all supporting documentation."

Given these regulatory requirements, the results of any testing and of any monitoring activities that are performed by the establishment may have an impact on the establishment's hazard analysis, whether or not such testing or monitoring is incorporated into an actual HACCP plan, referenced in a HACCP plan, or considered as separate activities. Therefore, records of these activities are subject to FSIS review and are to be available to FSIS personnel. Examples of such results and records include, but are not limited to, all records, results, and supporting documentation associated with

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each HACCP plan; records, results, and supporting documentation associated with prerequisite programs; and results and records of testing conducted for the establishment's business customers.

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

Inspection program personnel are to be aware of all monitoring and of all testing conducted by the establishment and should ask establishment management to make available for review the data that is generated by such monitoring or testing so that it is available when inspection program personnel are verifying HACCP records.

As part of performing HACCP 01 procedures, inspection program personnel are not only to randomly review HACCP records but any records from procedures that the establishment has performed or from prerequisite programs that are relevant to the ISP procedure being performed, particularly records of testing and monitoring (See FSIS Directive 5000.1, Revision 1, Chapter 2, Part I – HACCP Verification Methodology).

Inspection program personnel should determine whether the testing results suggest any food safety concerns that have not previously been recognized.

If, based on their review of establishment records, inspection program personnel have concerns about:

1. the design of testing, monitoring, or verification activities outside of a HACCP plan, or
2. concerns about results from such activities, procedures, or prerequisite programs,

they are to contact the Technical Service Center or raise the concern through supervisory channels. It may be determined that an Enforcement Investigation Analysis Officer needs to conduct a food safety assessment to assess such factors as what tests results reveal about food safety, and whether the design of testing, procedures, or prerequisite programs are adequately supported by the decisions made in the hazard analysis.

/s/ Philip S. Derfler

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